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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,456	09/30/2005	Nitin Bhalachandra Dharmadhikari	053180	3014

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
07/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,456	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/9/10, 5/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1 and 3-24 are pending. Claim 2 is cancelled.

Acknowledgment

Receipt of the amendments and arguments/remarks filed on 4/9/10 is acknowledged.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on April 9, 2010 and May 27, 2010 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statements were considered by the examiner. A signed copy of forms 1449 are enclosed herewith.

Withdrawn Rejections

The rejection of claims 19-22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1 and 3-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (US Patent No. 6,004,582) as evidenced by Amidon et al (US Patent No. 5,229,131) is maintained.

Faour et al teach a multi-layered osmotic device that allows for the immediate delivery of a first active agent followed by a monitored, continuous, controlled, and/or retarded delivery of a second active agent which is the same or different as the first active agent (column 1, lines 7-10). The osmotic device comprises a compressed core comprising a first active agent, an osmotic agent, and optionally PVP, a semi-permeable membrane surrounding the core and having a preformed passageway therein (the membrane is permeable to a fluid in the environment of use and substantially impermeable to the first active agent), and an inert water soluble polymer coat comprising poly (vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semi-permeable membrane and plugging the passageway in the wall (column 3, lines 49-65). The device also comprises an external coat comprising a second active agent for immediate release of the drug (column 3, lines 65-67). The active agent may be susceptible to decreased stability in the gastric environment, such as niacin, targeted to the intestine for local action, such as beclomethasone, or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as aspirin or naproxen (column 14, lines 29-30, 36; column 15, line 43).

Although Faour et al suggest the use of a water soluble polymer coat partially surrounding the semipermeable membrane that plugs the passageway; Faour et al do not explicitly teach a coating to substantially cover only the passageway.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Faour et al and substantially

cover only the passageway. One would have been motivated to do so to alter the release pattern of the dosage form, which is dependent on the needs of a particular patient population. A coating substantially only covering the passageway would result in a more immediate release of the core drug. Furthermore, it is noted that since "substantially" is not defined in the instant specification, the limitation of claim 1 allows for some coating to be applied elsewhere other than the passageway.

Regarding the newly added limitation, "wherein the swelling agent is present in the core composition in an amount such that, when the system is exposed to an aqueous environment, the swelling agent swells and exerts a pressure on the coat, thereby rupturing the coat to release contents of the core composition," it is noted that Faour et al suggest that its cores can include polyvinylpyrrolidone in an effective amount. According to the instant specification, polyvinylpyrrolidone is a suitable swelling agent in an amount of 5-95 wt.% (see spec. pg. 15, lines 4-27). Thus, since Faour et al suggest all the structural components of the instant claims including the instant swelling agent, it is the examiner's position that the drug delivery system of the prior art is capable of exerting pressure on the coat and rupturing the coat to release contents of the core composition when exposed to an aqueous environment. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. Thus, burden shifts to applicant to show

unexpected results by declaration or otherwise as *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).* The claimed properties would have been present once the composition was employed in its intended use as *In re Best, 195 USPQ 433*.

Regarding claims 10 and 17, which are directed to a dosage form exhibiting a pulsatile release, Faour's invention can have multiple separate drug layers, with multiple membranes and can release the beneficial agents in a concurrent manner. Thus, it is an expected property that Faour's system produces a pulsatile release (Figure 2; column 5, lines 58-64).

Regarding claims 12-15, Faour et al teach that the compositions may be designed to achieve pH-dependent and pH-independent delivery of the active agent (column 5, lines 58-61). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to create pH-dependent or pH-independent drug delivery systems with a reasonable expectation of success. One would have been motivated to do so since Faour et al suggest the creation of pH-dependent or pH-independent embodiments of the drug delivery system. Regarding the limitations of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon et al disclose that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus pH-dependent and pH-independent embodiments of Faour's invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon et al.

Regarding claim 21, the examiner notes that applicant has not defined a band or distinguished a band from a plug in the instant specification. Additionally, the examiner notes that like the plug, the band is comprised of an erodible polymer composition in the instant specification. As such, it is the position of the examiner that the water-soluble polymer coating of Faour et al would reasonably read on both a plug and a band blocking the passageway.

Response to Arguments

Applicant's arguments filed 4/9/10 have been fully considered but they are not persuasive.

Applicant argues that in the presently claimed invention, the core composition and the coat composition are designed such that, upon contact with the aqueous environment, the coat is ruptured because of the pressure generated within the core due to the presence of swelling agents. Applicant submits that the features of the presently claimed invention and its advantages are not taught or suggested in Faour, which teaches a conventional osmotic system wherein the release of the active ingredient in the core is controlled by the membrane and wherein the membrane is required to be maintained intact before and throughout the release period. Additionally, applicant argues that Amidon fails to remedy the deficiencies of Faour.

In response to applicant's arguments, it is noted that the newly added limitation of claim 1 is functional within a claim directed to a composition. Since the prior art suggests all the structural limitations of instant claim 1 (i.e., a core composition with a

swelling agent, a coat surrounding the core, a passageway, and a cover composition that covers only the passageway), the swelling agent would be capable of rupturing the coat to release the contents of the core composition. The examiner submits that the claim does not require that the swelling agent rupture the coating but only capable of performing the said intended function. Even if the claims required this limitation, applicant is directed to MPEP 2111.02, wherein it states that "the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." There is nothing that structurally distinguishes instant claim 1 from the compositions of Faour. Applicant has not recited specific amounts of components, particular swelling agents, pharmaceutically acceptable excipients, or the particular polymers of the coat and cover compositions, which could potentially differentiate the instant claims from the prior art.

Regarding applicant's argument that Amidon fails to remedy the deficiencies of Faour, it is noted that applicant's arguments regarding Faour are addressed above and are incorporated herein. Amidon was only cited to provide evidence that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying. Since applicant has not argued Amidon's teachings, it is the examiner's position that the rejection should be maintained for the reasons stated above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al (US Patent No. 5,474,784) as evidenced by Amidon et al (US Patent No. 5,229,131).

Stevens et al teach a controlled release device that can be administered orally and comprises a water impermeable capsule having at least one orifice wherein said orifice is closed by the insertion of a plug which is soluble or dispersible in water (column 1, lines 19-24). The contents of the hollow body are to be released as a pulse in the human body (claim 1). In example 5 of Stevens et al, the soluble plugs were comprised of the water-soluble polymer, polyvinylpyrrolidone (column 7, lines 4-7). The capsules are coated with an impermeable coating comprised of preferably polyvinyl chloride (column 5, lines 47-49). Additionally, the core comprises excipients including polyvinylpyrrolidone (column 2, lines 18-20). Furthermore, the active agent may be susceptible to decreased stability in the gastric environment, such as anti-ulcer agents, targeted to the intestine for local action, such as 5-amino salicylic acids, or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as piroxicam and diclofenac (column 14, lines 10-11, 24, & 29).

Regarding the newly added limitation, "wherein the swelling agent is present in the core composition in an amount such that, when the system is exposed to an aqueous environment, the swelling agent swells and exerts a pressure on the coat, thereby rupturing the coat to release contents of the core composition," it is noted that Stevens et al suggest that its cores can include polyvinylpyrrolidone in an effective amount. According to the instant specification, polyvinylpyrrolidone is a suitable swelling agent in an amount of 5-95 wt.% (see spec. pg. 15, lines 4-27). Thus, since Stevens et al teach all the structural components of the instant claims including the instant swelling agent, it is the examiner's position that the drug delivery system of the prior art is capable of exerting pressure on the coat and rupturing the coat to release contents of the core composition when exposed to an aqueous environment. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. Thus, burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).* The claimed properties would have been present once the composition was employed in its intended use as *In re Best, 195 USPQ 433*.

Regarding claims 12-15, Stevens et al teach that its compositions are designed to achieve pH-dependent and pH-independent delivery of the active agent by optionally incorporating pH-sensitive materials (column 2, lines 50-53). Regarding the limitations

of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon et al disclose that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus pH-dependent and pH-independent embodiments of Stevens' invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon et al. Furthermore, regarding instant claims 6-11 and 16-18, which are directed to the release of the drug delivery system, it is the position of the examiner that since Stevens et al teach a composition with the same components, the composition of Stevens would obviously exhibit the instant release as well as be capable of exhibiting the instant release.

Regarding claim 21, the examiner notes that applicant has not defined a band or distinguished a band from a plug in the instant specification. Additionally, the examiner notes that like the plug, the band is comprised of an erodible polymer composition in the instant specification. As such, it is the position of the examiner that the water-soluble polymer coating of Stevens et al would reasonably read on both a plug and a band blocking the passageway.

Response to Arguments

Applicant's arguments filed 4/9/10 have been fully considered but they are not persuasive.

Applicant argues that in the presently claimed invention, the core composition and the coat composition are designed such that, upon contact with the aqueous environment, the coat is ruptured because of the pressure generated within the core due to the presence of swelling agents. Applicant submits that the features of the presently claimed invention and its advantages are not taught or suggested in Stevens, which teaches that its plug is degraded and its impermeable membrane is maintained intact before and throughout the release period. Thus, applicant argues that the present claims are neither anticipated by nor obvious over Stevens.

In response to applicant's arguments, it is noted that the newly added limitation of claim 1 is functional within a claim directed to a composition. Since the prior art suggests all the structural limitations of instant claim 1 (i.e., a core composition with a swelling agent, a coat surrounding the core, a passageway, and a cover composition that covers only the passageway), the swelling agent would be capable of rupturing the coat to release the contents of the core composition. The examiner submits that the claim does not require that the swelling agent rupture the coating but only capable of performing the said intended function. Even if the claims required this limitation, applicant is directed to MPEP 2111.02, wherein it states that "the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." There is nothing that structurally distinguishes instant claim 1 from the compositions of Stevens. Applicant has not recited specific

amounts of components, particular swelling agents, pharmaceutically acceptable excipients, or the particular polymers of the coat and cover compositions, which could potentially differentiate the instant claims from the prior art.

Thus, it is the examiner's position that the rejection should be maintained for the reasons stated above.

Conclusion

Claims 1 and 3-24 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643